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Special 510(k) Summary of Safety and Effectiveness
Line extension to Neurolac nerve guide

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Date Prepared:	20 September 2011

General Provisions:	Trade Name: Neurolac® Nerve guide Common Name: Nerve guide Classification Name: Nerve Cuff, 21 CFR 882.5275 Device Classification: Class II

Predicate Device:	• Neurolac	Polyganics BV	K032115

Performance Standards	For the Nerve Cuff performance, the FDA, under section 514 of the Food, Drug and Cosmetic Act, has not established standards.

Indications for Use	The Neurolac® nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.

Device Description

Neurolac® is designed to be a flexible and transparent resorbable poly(DL-lactide-co-ε-caprolactone) tube to provide a protective environment for peripheral nerve regeneration after injury and to create a conduit to guide axonal growth across a nerve gap.

Neurolac® nerve guides are provided sterile in Tyvek pouch packages and retainer in a variety of sizes.

The modification in this submission concerns a line extension to the predicate devices with a thinner wall thickness.

Performance Data:

In vitro testing for this line extension demonstrated that the technological characteristics and performance criteria of the additional thinner-walled Neurolac nerve guides are comparable to the current cleared Neurolac nerve guides and that they can perform in a manner equivalent to Neurolac devices currently on the market for the same intended use. The results of the in vitro testing are summarized below:

Properties		Cleared Neurolac nerve guides	Neurolac with 37% wall thickness reduction
Dimensional changes	Inner diameter	Lumen maintained till week 10-11	Lumen maintained till week 10-11
	Outer diameter	Gradual increase	Gradual increase
	Wall thickness	Gradual increase in outward direction	Gradual increase in outward direction
Weight changes	Swelling (water uptake)	Stable in initial weeks and then gradual increase	Stable in initial weeks and then gradual increase
	Weight loss	After week 10-11	After week 10-11
Analysis	NMR	Degradation prodcuts after week 12	Degradation products after week 12
	DSC	Gradual decrease in T_g	Gradual decrease in T_g
	Intrinsic Viscosity	Slow and gradual decrease	Slow and gradual decrease
Mechanical properties		Stable for initial 10-11 weeks	Stable for initial 10-11 weeks
Flexural properties		Stable for initial 10-11 weeks	Stable for initial 10-11 weeks
Compression properties		Stable for initial 10-11 weeks	Stable for initial 10-11 weeks
Suturability testing		Difficult suturing	Easy suturing

Summary of Substantial Equivalence

The design, materials, fundamental technology and intended use (safety and efficacy) featured with the Neurolac® Nerve Guide are substantially equivalent to those featured with the following cleared device: Neurolac nerve guides (K032115; Polyganics BV). The basis for equivalence is demonstrated by the comparisons in the following table:

	Neurolac nerve guide thinner-walls (this submission)	**Neurolac nerve guide** (K032115)
Intended use	Reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.	Reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.
Material	poly(DL-lactide-co-ε-caprolactone)	poly(DL-lactide-co-ε-caprolactone)
Design	Tube	Tube
Sizes	1.5 – 3mm ID 3cm length	1.5 – 3mm ID 3cm length
Sterilization	EtO	EtO
Shelf-life	42 months	42 months
Packaging	Single use, polycar-bonate tray, single tyvek pouch, cardboard box.	Single use, polycar-bonate tray, single tyvek pouch, cardboard box.

Differences between the devices do not raise any significant issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

OCT 2 0 2011

Polyganics BV
c/o Betty IJmker
Manager Regulatory Affairs
Rozenburglaan 15A
9727 DL Groningen
The Netherlands

Re: K112267
Trade/Device Name: Neurolac Nerve Guide
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: II
Product Code: JXI
Dated: September 20, 2011
Received: September 23, 2011

Dear Ms. Ijmker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K112267

Device Name Neurolac® nerve guide

Indications for Use The Neurolac nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____x____ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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